

- B) Osborn does not teach that the syringe barrel handle member (gripping device 60 in Osborn) is attached to the rear terminus of the hollow syringe barrel. The gripping device 60 of Osborn is attached to the periphery of cylinder 50. Primary Examiner Hayes indicated that Examiner Ghafoorian should reconsider Osborn with respect to this limitation in claim 1. The Examiner is directed to the drawings; Page 5, lines 1-3; Page 35, lines 20-22; and Page 36, lines 2-4 and 8-12 of Applicant's specification.
- C) Osborn does not disclose an attached piston. The Examiner indicated that, in Osborn, the tapering of the plunger 30 was the piston and that it was attached. The Applicant pointed out that the tapering of the plunger 30 in the Osborn tampon dispenser was not an "attached piston" but was a continuation of the plunger 30; not different pieces requiring attachment.
- D) Osborn does not teach or show an attached piston that contacts and is capable of maintaining a tight seal along the entire length of the syringe barrel cavity as claimed in Applicant's claim 1.
- E) The bellows of the Osborn reference is not attached to the rear face surface of the syringe barrel handle member (gripping device 60 in Osborn). Applicant cited column 4, lines 30-34, which teaches that the bellows of Osborn is attached to the cylinder 50. Primary Examiner Hayes indicated that Examiner Ghafoorian should reconsider Osborn with respect to this limitation.

II. With regard to the Park reference, Applicant pointed out during the interview that:

- A) Park does not disclose a corrugated sheath attached to a rearward face surface of a syringe barrel handle member that is, in turn, attached to the syringe barrel rear terminus, as claimed by Applicant in claim 1. Instead, Park teaches attachment of the bellows to a stopper. Primary Examiner Hayes indicated that Examiner Ghafoorian should reconsider the Park reference with respect to this limitation. The Applicant also requested that the Examiner clarify how the Park reference is being interpreted.

Examiner Ghafoorian indicated in the Interview Summary "to potentially review the art once Applicant submits an after Final Amendment." However, Applicant does not believe that the cited art warrants amendment of the claims.

Information Disclosure Statement:

It is noted that the Office Action Summaries of April 10, 2003 and September 10, 2003 did not include a copy of the initialed, signed, and dated Information Disclosure Statement (PTO-1449), which was submitted with the originally filed application dated 01/24/2002. Please see the copies of Applicant's Utility Patent Application Transmittal and Applicant's returned Post Card Receipt that were submitted with Applicant's last response dated July 7, 2003, demonstrating Applicant's filing of the referenced IDS and references. The Examiner is kindly requested to review the references submitted and provide a copy of the signed, initialed, and dated Information Disclosure Statement (PTO-1449) to Applicant.

Response to Election/Restriction Requirement:

In response to the Final Office Action dated September 10, 2003 on the above-identified application, please reconsider Applicant's traversal of the Restriction Requirement. Applicant's traversal is on the grounds that the species recited in the Restriction Requirement are not properly grouped. The Examiner indicated in the Office Action of April 10, 2003, "the Applicant alleges that Figures 3-8b are one species and Figures 9-13b are another species." However, the Applicant has not made this assertion. The species submitted by the Applicant are repeated here as follows:

Species	Figures	Claims Readable on Species	Pages at which Species Supported in Specification	Description of Species
Species A	1 and 2	1, 4, 7, 8, 13, 15, 16, 17, 21-26, new claims 27-32	Page 31, lines 9-16	Syringe with corrugated sheath
Species B	3 and 4	2, 5, 9, 10, 14	Page 31, lines 17-21	Syringe having straight and corrugated barrel segments
Species C	5, 6a, 6b	3, 6, 11, 12, 18, 19	Page 32, lines 3-13	Syringe having mating concentric plunger and syringe barrels
Species D	7, 8a, 8b	3, 6, 11, 12, 18, 19	Page 32, lines 14-22	Syringe having concentric syringe barrels and mating plunger member
Species E	9, 10, 11	20	Page 33, lines 3-12	Contaminant shield molded in syringe barrel cavity
Species F	12	20	Page 33, lines 13-16	Threaded end-cap contaminant shield
Species G	13a	20	Page 33, lines 17-20	End-cap with lip or flange
Species H	13b	20	Page 33, lines 21-23	End-cap without extending wall

The claims readable on each of Species A-H and the corresponding support describing each of the Species A-H, as provided by the specification, is set forth above. It is noted that claims 3, 6, 11, 12, 18, and 19 are generic to Species C and D and Claim 20 is generic to Species E, F, G, and H. Applicant respectfully requests that the Examiner kindly reconsider the original Restriction Requirement in view of Applicant's Species grouping of the original and newly submitted claims.

Response to Rejections:

1. Claims 1, 7, 8, 13, 16, 21, 23-27, and 29-32 have been rejected under 35 U.S.C. 102(b) as being anticipated by Osborn, III et al., Patent No. 5,817,047.

- **Specifically regarding the rejection of claim 1:**

Initially, it is noted that Osborn, III et al. is non-analogous art. The claimed syringe of the instant invention has specific structural limitations and performs specific functions, as defined by the specification and not disclosed by Osborn, III et al. Osborn, III et al. is drawn to a *combination tampon and tampon inserter* and not to a syringe. Applicant's invention is not drawn to tampons and devices used to dispense and insert tampons. The syringe of the instant invention is not used for holding or inserting tampons. Applicant's invention is drawn to a syringe. Applicant's claimed syringe is not used to hold, insert or dispense tampons. Applicant's specification clearly defines how the structures of the syringe function. Nowhere is the instant syringe intended as a holder, inserter, or dispenser of tampons. It is also noted that the Osborn, III et al. reference makes no mention of the term *syringe*. Osborn, III et al. do not equate tampon inserters to syringes. This is a clear structural and functional difference between the Osborn, III et al. reference and Applicant's claimed invention.

Note that Applicant's claim 1 recites that the plunger shaft has an attached piston, wherein said attached piston is capable of slidably engaging and maintaining a tight seal with the inner wall surfaces of the hollow syringe barrel cavity along the entire length of the syringe barrel cavity during withdrawal and advancement of the plunger shaft and attached piston. The examiner rejected the limitations of claim 1 as being taught by Osborn, III et al. Osborn, III et al., do not disclose an *attached* piston. The Examiner's response to this argument in the Final Office Action indicated that the tapered portion of the plunger 30 was being relied upon as meeting the limitation of an attached piston. The tapered portion of the plunger 30 of the Osborn, III et al. reference

is not a piston, but is actually a continuation of the plunger 30. The plunger shaft and piston claimed by Applicant are different parts, which are attached together. The tapered portion of plunger 30 in the Osborn III, et al. reference is not attached to the plunger 30, *but is plunger 30*. This is a clear structural difference between the Osborn, III et al. reference and Applicant's claim. The piston of Applicant's invention performs a specific function as claimed. The piston claimed by Applicant is not disclosed in the Osborn, III et al. reference. Accordingly, the tampon dispenser of Osborn, III et al. is unable to function as the syringe claimed by Applicant. Further, the tapered portion of the plunger 30 taught by Osborn, III et al. is not capable of functioning as a piston in a syringe, as claimed by Applicant.

Also, Osborn, III et al., do not disclose a plunger shaft having an attached piston capable of slidably engaging and maintaining a tight seal with the inner wall surfaces of the hollow syringe barrel cavity along the entire length of the syringe barrel cavity during withdrawal and advancement of the plunger shaft and attached piston, as recited in claim 1. In fact, the Osborn, III et al. reference does not show or recite that the tapered portion of the plunger 30 contacts and forms a tight seal with the walls of the cylinder 50. Advancement of the plunger 30 in the Osborn, III et al. reference cannot be considered to produce or maintain a tight seal with the length of the cylinder 50. It is noted that the reference does not disclose that withdrawal of the plunger 30 is possible – it certainly is not warranted. It is noted that the tampon positioned in the cylinder 50 of the tampon dispenser impedes advancement of the plunger 30 until the forward end of the cylinder 50 is ruptured. Applicant's syringe does not rupture during advancement of the plunger shaft, nor does it dispense tampons. Thus, the tapered portion of plunger 30 does not slidably engage and maintain a tight seal with the cylinder 50 of the tampon dispenser during advancement or withdrawal of the plunger 30. The instant invention, however, claims an attached piston that *contacts* and slidably engages and maintains a tight seal with the inner wall surfaces of the hollow syringe barrel cavity along the entire length of the syringe barrel cavity during withdrawal and advancement of the plunger shaft and piston.

Additionally, the Osborn, III et al. reference does not recite a corrugated sheath attached to a rearward end face surface of said syringe barrel handle member, as claimed by Applicant. The Examiner will note that the Osborn, III et al. reference discusses at column 4, lines 30-34, with reference to Figure 2, that attachment of the bellows 100 is to cylinder 50 and not to gripping means 60. Note that the limitations of

Applicant's claim 1 require that the corrugated sheath be attached to a rearward end face surface of said syringe barrel handle member; the handle member is, in turn, permanently attached to the rearward end terminus of the syringe barrel. However, the Osborn, III et al. reference does not teach a syringe barrel handle member attached to the rear terminus of the syringe barrel or a corrugated sheath attached to a rearward end face surface of the syringe barrel handle member. These are clear structural differences between Applicant's claimed invention and the Osborn, III et al. reference. Applicant presented this argument at the interview on November 6, 2003 and Primary Examiner Hayes indicated that Examiner Ghafoorian should reconsider the Osborn, III et al. reference with regard to this limitation.

A claim is anticipated by a reference only if each and every element as set forth in the claim is found in the reference. For these reasons, Applicant submits that Osborn, III et al. do not anticipate the claimed subject matter of claim 1. Accordingly, the Examiner has not shown that Applicant's claimed product is structurally the same as that of Osborn III, et al. and is requested to withdraw this rejection.

• **Specifically regarding the rejection of claim 7:**

The rejection of claim 7 should be withdrawn because the Osborn, III et al. reference does not recite or show that the plunger shaft handle member is *molded* to the rear terminus of the plunger shaft, as claimed by Applicant. The Examiner will note that the Osborn, III et al. reference discusses at column 6, lines 33-36, with reference to Figures 1-3, that a seal 90 is located at the rear end of the plunger 30. The seal 90 is separate from the gripping means 70. Note that the gripping means 70 is located on the longitudinal periphery of the plunger 30 and not at the rearward end terminus of the plunger 30. The periphery of the plunger 30 is not the same surface as the rearward end terminus surface. It should be noted that even Osborn, III et al. teaches this fact when Osborn, III et al. indicates that seal 90 is located at the rear end of the plunger 30. This is also apparent from the drawings because the hatch marks for the gripping means 70 are not present at the rear terminus of the plunger 30. Note that seal 90 could not be located at the rearward end terminus of the plunger 30, as indicated by Osborn, III et al., if the gripping means 70 were located there. The limitation of Applicant's claim 7 requires that the plunger shaft handle member be located at the rear face terminus of the plunger shaft -- not located on the longitudinal periphery, as in the Osborn, III et al. reference. This is a clear structural difference between the Osborn, III et al. reference

and Applicant's claimed invention. This argument was presented in the response filed July 7, 2003 by Applicant following the First Office Action, but has not been addressed by the Examiner.

Further, the reference does not teach that the plunger shaft handle member is *molded* to the rear face terminus of the plunger shaft. The Osborn, III et al. reference makes no attempt to discuss the type of attachment, if any, between the plunger shaft handle member and the plunger shaft. The Examiner indicates this claim limitation to be a product-by-process limitation. However, the claim does not recite an active process step, but rather describes the type of attachment present or existing between the plunger shaft handle member and the rear face terminus of the plunger shaft. A claim is anticipated by a reference only if each and every element as set forth in the claim is found in the reference. The Osborn, III et al. reference does not anticipate the limitations of claim 7. Accordingly, the Examiner has not shown that Applicant's claimed product is structurally the same as that of Osborn III, et al. and is requested to withdraw this rejection.

• **Specifically regarding the rejection of claim 8:**

The rejection of claim 8 should be withdrawn because the Osborn, III et al. reference does not recite or show that the corrugated sheath is *molded* to the plunger shaft handle member, as claimed by Applicant. The limitation of claim 8 describes the type of structural attachment present or existing between the corrugated sheath and the plunger shaft handle member. The Osborn, III et al. reference is silent and makes no attempt to discuss the type of attachment relationship between the bellows 100 and the gripping means 70 or plunger 30, or even if an attachment is present. One cannot conclude from the drawings that an attachment exists between bellows 100 and gripping means 70. The reference must recite the claimed limitation – it cannot be assumed to be present. This argument was presented by Applicant in the response of July 7, 2003 following the First Office Action, but has not been addressed by the Examiner.

A claim is anticipated by a reference only if each and every element as set forth in the claim is found in the reference. The Osborn, III et al. reference does not anticipate the limitations of claim 8. Accordingly, the Examiner is requested to withdraw this rejection.

- **Specifically regarding the rejection of claim 13:**

The rejection of claim 13 should be withdrawn for the reasons stated above with respect to claim 1, as claim 13 depends directly from claim 1.

- **Specifically regarding the rejection of claim 16:**

The rejection of claim 16 should be withdrawn because the Osborn, III et al. reference does not recite that the syringe barrel handle member is *molded* to or *formed* on the rearward end terminus of a syringe barrel, as claimed. The limitation of claim 16 describes the type of structural attachment present or existing between the syringe barrel rearward end terminus and the syringe barrel handle member. In fact, the Osborn, III et al. reference recites only the presence of a gripping means 60 and a tampon dispenser. The gripping means 60 is located on the longitudinal periphery of the tampon-dispensing cylinder 50. The Examiner will note that the Osborn, III et al. reference discusses at column 4, lines 30-34, with reference to Figure 2, that attachment of the bellows 100 is to cylinder 50 – not to gripping means 60. Accordingly, attachment of bellows 100 to cylinder 50 would not be possible if gripping means 60 were attached to the terminus of the cylinder 50. The gripping means 60 in the Osborn, III et al. reference is located on the longitudinal periphery of the cylinder 50 and not at the rearward terminus of cylinder 50. This is also apparent from the drawings because the hatch marks for the gripping means 60 are not present at the terminus of the cylinder 50. The limitation of Applicant's claim requires that the syringe barrel handle member be molded or formed on the rearward end terminus of the syringe barrel. Neither the reference nor the Figures of Osborn, III et al. recite or show a syringe barrel handle member molded to or formed on the rearward end terminus of a syringe barrel. This is a clear structural difference between the cited art and Applicant's claim.

Accordingly, the Examiner has not shown that Applicant's claimed product is structurally the same as that of Osborn III, et al. and the Examiner is requested to withdraw this rejection.

- **Specifically regarding the rejection of claim 21:**

The rejection of claim 21 should be withdrawn for the reasons stated above with respect to claim 1, as claim 21 depends directly from claim 1.

• **Specifically regarding the rejection of claim 23:**

The rejection of claim 23 should be withdrawn because the Osborn, III et al. reference does not recite using a syringe barrel, plunger shaft, and corrugated sheath that is colored or tinted, as claimed by Applicant. It is unclear how the claim limitations are met by the Osborn, III et al. reference and what teaching in the reference that the Examiner is relying on to meet these limitations. This is a clear structural difference between the cited art and Applicant's claim. This argument was presented by Applicant in the response filed July 7, 2003 following the First Office Action, but has not been addressed by the Examiner.

A claim is anticipated by a reference only if each and every element as set forth in the claim is found in the reference. Because the Osborn, III et al. reference is deficient for the reasons advanced above, the Osborn, III et al. reference does not anticipate the limitations of claim 23. Accordingly, the Examiner has not shown that Applicant's claimed product is structurally the same as that of Osborn III, et al. and the Examiner is requested to withdraw this rejection.

• **Specifically regarding the rejection of claim 24:**

The rejection of claim 24 should be withdrawn because the Osborn, III et al. reference does not recite a removable closure cap, as claimed by Applicant. In fact, there is no motivation, nor would there be a reason to provide, a removable closure cap. The tampon-dispensing device of Osborn, III et al. is designed to maintain a sealed gas inside the device. A removable closure cap, as recited in Applicant's claim 24, used in Osborn's tampon dispensing device would release the sealed gas if removed. The purpose of the closure cap in Applicant's claimed invention is for mating with and closing the forward end opening so as to maintain sterility of the inner walls of the syringe barrel and to retain materials in the syringe barrel. It is unclear how the Osborn, III et al. reference meets the limitations of claim 24. A claim is anticipated by a reference only if each and every element as set forth in the claim is found in the reference. The Osborn, III et al. reference does not anticipate the limitations of claim 24. This argument was presented by Applicant in the response of July 7, 2003 following the First Office Action, but has not been addressed by the Examiner.

Accordingly, the Examiner has not shown that Applicant's claimed product is structurally the same as that of Osborn III, et al. and the Examiner is requested to withdraw this rejection.

- **Specifically regarding the rejection of claim 25:**

The rejection of claim 25 should be withdrawn because the Osborn, III et al. reference does not recite a removably attachable needle or permanently attached needle, as claimed by Applicant. In fact, there is no motivation nor would there be a reason to provide a removably attachable needle to the tampon dispensing device of Osborn or to provide the tampon-dispensing device with a permanently attached needle. It is unclear how the claimed limitations are met by the Osborn, III et al. reference and what teaching in the Osborn III, et al. reference the Examiner is relying on to meet these limitations. A claim is anticipated by a reference only if each and every element as set forth in the claim is found in the reference. The Osborn, III et al. reference does not anticipate the limitations of claim 25. This argument was presented by Applicant in the response of July 7, 2003 following the First Office Action, but has not been addressed by the Examiner.

Accordingly, the Examiner has not shown that Applicant's claimed product is structurally the same as that of Osborn III, et al. and the Examiner is requested to withdraw this rejection.

- **Specifically regarding the rejection of claim 26:**

The rejection of claim 26 should be withdrawn because the Osborn, III et al. reference does not recite a brace means, as claimed by Applicant. The brace means of the instant invention functions to maintain the plunger shaft in a withdrawn position such that the substance in the syringe is not expelled or ejected from the syringe barrel. The brace means restricts the plunger member from movement along and within the syringe barrel until the brace means is removed. This is a clear structural difference between Applicant's claimed subject matter and the Osborn, III et al. reference. It is unclear how the claimed limitations are met by the Osborn, III et al. reference, and what teaching in the reference the Examiner is relying on to meet the limitation. A claim is anticipated by a reference only if each and every element as set forth in the claim is found in the reference. The Osborn, III et al. reference does not anticipate the limitations of claim 26. This argument was presented by Applicant in the response of July 7, 2003 following the First Office Action, but has not been addressed by the Examiner.

Accordingly, the Examiner has not shown that Applicant's claimed product is structurally the same as that of Osborn III, et al. and the Examiner is requested to withdraw this rejection.

• **Specifically regarding the rejection of claim 27:**

The rejection of claim 27 should be withdrawn because the Osborn, III et al. reference does not recite or show a syringe having a forward end that tapers to a reduced diameter neck, where the reduced diameter neck forms a permanent forward end opening, as claimed by Applicant. These structural limitations of the instant invention provide an entrance/exit port for flowable materials to be drawn into and expelled or ejected from the syringe barrel. The Osborn, III et al. reference does not teach a syringe having a reduced diameter neck that forms a permanent forward end opening as required by the claim. It is unclear how the claimed limitations are met by the Osborn, III et al. reference, and what teaching in the reference the Examiner is relying on to meet the limitations. A claim is anticipated by a reference only if each and every element as set forth in the claim is found in the reference. The Osborn, III et al. reference does not anticipate the limitations of claim 27. Accordingly, the Examiner has not shown that Applicant's claimed product is structurally the same as that of Osborn III, et al. and the Examiner is requested to withdraw this rejection.

• **Specifically regarding the rejection of claim 29:**

The rejection of claim 29 should be withdrawn because the Osborn, III et al. reference does not recite or show a syringe (the device of Osborn III, et al. is a tampon dispenser and not a syringe) having a corrugated sheath which does not automatically recoil after being lengthened or compressed. The Osborn, III et al. reference is silent regarding this limitation and cannot be assumed to be present in bellows 100. It is unclear how the claimed limitations are met by the Osborn, III et al. reference, and what teaching in the reference that the Examiner is relying on to meet this limitation. A claim is anticipated by a reference only if each and every element as set forth in the claim is found in the reference. The Osborn, III et al. reference does not anticipate the limitations of claim 29. Accordingly, the Examiner has not shown that Applicant's claimed product is structurally the same as that of Osborn III, et al. and the Examiner is requested to withdraw this rejection.

• *Specifically regarding the rejection of claim 30:*

The rejection of claim 30 should be withdrawn because the Osborn, III et al. reference does not recite a corrugated sheath enclosing the length of the plunger existing between the rearward end face surface of said syringe barrel handle member, and the forward face of the plunger handle member, as claimed by Applicant. Regarding the attachment of the corrugated sheath to the rear face surface of the syringe barrel handle member, the Examiner will note that the Osborn, III et al. reference discusses at column 4, lines 30-34, with reference to Figure 2, that attachment of the bellows 100 is to cylinder 50 and not to gripping means 60. Note that the limitations of Applicant's claim 1, from which claim 30 depends, require that the corrugated sheath be attached to the rearward end face surface of said syringe barrel handle member; the handle member is, in turn, permanently attached to the rearward end terminus of the syringe barrel. Regarding attachment of the bellows 100 to the plunger shaft handle member, the Osborn, III et al. reference does not recite or show that the bellows 100 is molded to the gripping means 70, such that the bellows 100 encloses the length of the plunger existing between the forward face of gripping means 70, as claimed by Applicant. The Osborn, III et al. reference is silent and makes no attempt to discuss an attachment relationship between the bellows 100 and the gripping means 70, or even if an attachment is present. One cannot absolutely conclude from the drawings if attachment exists between bellows 100 and gripping means 70 or between the bellows 100 and the plunger 30. To meet the limitation of claim 30, Osborn must recite attachment between the gripping mean 70 to the bellows 100. The reference must recite the claimed limitation – it cannot be assumed to be present. Accordingly, it cannot be determined precisely what section of the plunger shaft the bellows 100 is enclosing in Osborn, III et al. because the attachment of the forward end of bellows 100 is to the cylinder 50 and the point of attachment of the rearward end of bellows 100 is undisclosed and cannot be determined. The Osborn reference certainly does not meet the limitations of claim 30. These are clear and patentable structural distinctions between Applicant's claimed invention and the Osborn, III et al. reference. It is unclear how the claimed limitations are met by the Osborn, III et al. reference, and what teaching in the reference the Examiner is relying on to meet these limitations. A claim is anticipated by a reference only if each and every element as set forth in the claim is found in the reference. The Osborn, III et al. reference does not anticipate the limitations of claim 30. Accordingly, the Examiner has not shown that Applicant's

claimed product is structurally the same as that of Osborn III, et al. and the Examiner is requested to withdraw this rejection.

- *Specifically regarding the rejection of claim 31:*

The rejection of claim 31 should be withdrawn because the Osborn, III et al. reference does not teach a rearward end opening for entrance and exit of the plunger shaft; specifically, withdrawal of the plunger 30 from cylinder 50. Withdrawal of the plunger shaft in the Osborn, III et al. reference, if at all possible, would leave the tampon spaced apart from the plunger 30. The intent and purpose of the Osborn, III et al. reference is to dispense the tampon 20 by pushing plunger 30 towards gripping means 60. In fact, the reference does not disclose that withdrawal of the plunger 30 is possible and does not recite anywhere in the reference that withdrawal of the plunger 30 is performed or even feasible – it certainly is not warranted in order to dispense tampons. It is also noted that the bellows 100 plays a role in whether the plunger can even be withdrawn. A bellows 100 that is fully extended or elongated will not allow further withdrawal, only advancement – which is the operation Osborn intends the tampon dispenser to perform. Note that the Osborn, III et al. reference never teaches or suggests withdrawal of the plunger 30.

The reference must recite the claimed limitation – it cannot be assumed that the plunger 30 of the tampon-dispensing device can be withdrawn from the cylinder 50. It certainly should not be assumed where there is no motivation or rationale for performing the function. Thus, the structure relied upon by the Examiner is not capable of performing the claimed function. These are clear and patentable structural and functional distinctions between Applicant's claimed invention and the Osborn, III et al. reference. It is unclear how the claimed limitations are met by the Osborn, III et al. reference, and what teaching in the reference that the Examiner is relying on to meet these limitations. A claim is anticipated by a reference only if each and every element as set forth in the claim is found in the reference. The Osborn, III et al. reference does not anticipate the limitations of claim 31. Accordingly, the Examiner has not shown that Applicant's claimed product is structurally the same as that of Osborn III, et al. and the Examiner is requested to withdraw this rejection.

• **Specifically regarding the rejection of claim 32:**

The rejection of claim 32 should be withdrawn because the Osborn, III et al. reference does not recite, disclose, or require the use of an attached piston. Accordingly, the plunger 30 does not extend between an attached piston and a plunger handle member. Applicant presented the argument that the tapered portion of the plunger 30 is not an attached piston at the interview on November 6, 2003 with regard to claim 1, and the Examiner indicated that the tapered portion of the plunger 30 was being relied on as meeting the limitation of an attached piston. However, the tapered portion of the plunger 30 of the Osborn, III et al. reference is not a piston, but is actually the plunger 30. The plunger shaft and piston claimed by Applicant are different parts, which are attached together. The tapered portion of plunger 30 in the Osborn III, et al. reference is not attached to the plunger 30, *but is plunger 30*. The term "attached" has meaning. This is a clear structural difference between the Osborn, III et al. reference and Applicant's claim. Further, the tapered portion of the plunger 30 taught by Osborn, III et al. is not capable of functioning as a piston in a syringe, as claimed by Applicant and taught by Applicant's specification. Accordingly, the Osborn, III et al. reference does not teach that the plunger shaft is a single and continuous component extending between a piston and a plunger shaft handle member. This is a clear and patentable structural difference between Applicant's claimed invention and the Osborn, III et al. reference. It is unclear how the Osborn, III et al. reference meets the claimed limitations. A claim is anticipated by a reference only if each and every element as set forth in the claim is found in the reference. The Osborn, III et al. reference does not anticipate the limitations of claim 32. Accordingly, the Examiner has not shown that Applicant's claimed product is structurally the same as that of Osborn III, et al. and the Examiner is requested to withdraw this rejection.

2. Claims 1, 7, 8, 13, 16, and 21-32 have been rejected under 35 U.S.C. 102(e) as being anticipated by Park, Patent No. 6,475,193.

• **Specifically regarding the rejection of claim 1:**

Claim 1 recites that the syringe has a syringe barrel handle member permanently attached to the syringe barrel rearward end terminus. Also, claim 1 recites that the corrugated sheath is attached to a forward face surface of a plunger shaft handle member and a rearward face surface of said permanently attached syringe barrel handle

member. The Park reference does not disclose a corrugated sheath attached to a rearward face surface of a syringe barrel handle member that is, in turn, permanently attached to the rearward end terminus of the syringe barrel. Note that the forward end of the bellows 86 of the Park reference is “fixed” to the stopper 80 (see Park reference: column 4, lines 63-67). Stopper 80 can be moved and is not a syringe barrel handle member and is not permanently attached to the rearward end terminus of the syringe barrel (see column 4, lines 50-53; column 5, lines 46-48). In fact, it is the intention of Park to provide a continuous injecting apparatus, which enables a disposal syringe to be removably mounted in the injection apparatus (see column 2, lines 9-12). It is the intention of Park to provide a continuous injection apparatus that can be disassembled and reassembled. Note also that the bellows 86 is not attached to a syringe barrel handle member; it is attached to a stopper. These are clear structural differences between Applicant’s claimed subject matter and the Park reference. For these reasons, Applicant submits that the Park reference does not anticipate the claimed subject matter of claim 1. A claim is anticipated by a reference only if each and every element as set forth in the claim is found in the reference. The Examiner has not shown that Applicant’s claimed product is structurally the same as that of Park. Accordingly, the Examiner is requested to withdraw this rejection.

• **Specifically regarding the rejection of claim 7:**

The rejection of claim 7 should be withdrawn because the Park reference does not teach that the plunger shaft handle member is *molded* to the rear terminus of the plunger shaft, as claimed by Applicant. The Examiner indicates this claim limitation is a product-by-process limitation. However, the claim does not recite any active process steps, but rather describes the type of attachment present or existing between the plunger shaft handle member and the rear terminus of the plunger shaft. It is unclear how the claim limitations are met by the Park reference and what teaching in the reference the Examiner is relying on to meet the limitation. There is no discussion on record by the Examiner as to how the Park reference is being interpreted to meet the claimed limitations. Accordingly, the Examiner is requested to withdraw this rejection.

• **Specifically regarding the rejection of claim 8:**

Claim 8 recites that the rear terminus of the corrugated sheath is *molded* to the plunger shaft handle member. The limitation of claim 8 is the type of attachment

present or existing between the corrugated sheath and the plunger shaft handle member. The Examiner will note that the Park reference discusses at column 4, lines 63-67, with reference to Figure 4, that the bellows 86 is "hooked" in the groove 76b. Note that "hooking" is not the same structure attachment as *molded*, as recited in claim 8. The Examiner indicates that the term "*molded*" is a product-by-process limitation. However, Claim 8 does not recite any active process steps, but rather describes the type of attachment present or existing between the corrugated sheath and the plunger shaft handle member. Park's intention is to provide a continuous injection apparatus that can be disassembled and reassembled. Applicant's syringe is not a continuous injection apparatus and cannot be disassembled and reassembled. There is no discussion on record by the Examiner as to how the Park reference is being interpreted to meet the claimed limitations. The limitations of claim 8 are clear structural difference from the teachings of the Park reference. A claim is anticipated by a reference only if each and every element as set forth in the claim is found in the reference. The Park reference does not anticipate the limitations of claim 8. Accordingly, the Examiner is requested to withdraw this rejection.

- *Specifically regarding the rejection of claim 13:*

The rejection of claim 13 should be withdrawn for the reasons stated above with respect to claim 1, as claim 13 depends directly from claim 1.

- *Specifically regarding the rejection of claim 16:*

The rejection of claim 16 should be withdrawn because the Park reference does not recite that the syringe barrel handle member is *molded* to or *formed* on the rearward end terminus of the syringe barrel, as claimed by Applicant. The Examiner indicates that molded is a product-by-process limitation. The limitation of claim 16 recites the type of attachment between the syringe barrel handle member and the rearward end terminus of the syringe barrel. Claim 16 does not recite a product-by-process limitation. Claim 16 does not recite any active process steps, but rather describes the type of attachment present or existing between the syringe barrel handle member and the rearward end terminus of the syringe barrel. Note that the limitations of Applicant's claim 16 require that the syringe barrel handle member be molded to or formed on the rearward end terminus of the syringe barrel. This is a clear structural difference between Applicant's claim and the Park reference. A claim is anticipated by

a reference only if each and every element as set forth in the claim is found in the reference. The Park reference does not anticipate the limitations of claim 16 or the combination of claims 1 and 16. Accordingly, the Examiner is requested to withdraw this rejection.

- **Specifically regarding the rejection of claim 21:**

The rejection of claim 21 should be withdrawn because the bellows 86 of the Park reference does not expand or collapse along the longitudinal axis of the plunger shaft (syringe rod 3 in Park), but rather rod 72. This is a clear structural difference between Applicant's claim and the Park reference. A claim is anticipated by a reference only if each and every element as set forth in the claim is found in the reference. The Park reference does not anticipate the limitations of claim 21 or the combination of claims 1 and 21. Accordingly, the Examiner is requested to withdraw this rejection.

- **Specifically regarding the rejection of claim 22:**

The rejection of claim 22 over Park should be withdrawn for the reasons stated above with respect to claim 1, as claim 22 depends directly from claim 1.

- **Specifically regarding the rejection of claim 23:**

The rejection of claim 23 should be withdrawn because the Park reference does not recite using a syringe barrel, plunger shaft, and corrugated sheath that is colored or tinted, as claimed by Applicant. It is unclear how the claim limitations are met by the Park reference and what teaching in the reference the Examiner is relying on to meet the limitation. These are clear structural differences between Applicant's claim and the park reference. This argument was presented by Applicant following the First Office Action, but has not been addressed by the Examiner.

A claim is anticipated by a reference only if each and every element as set forth in the claim is found in the reference. The Park reference does not anticipate the limitations of claim 23. Accordingly, the Examiner is requested to withdraw this rejection.

- **Specifically regarding the rejection of claim 24:**

The rejection of claim 24 should be withdrawn because the Park reference does not recite a removable closure cap, as claimed by Applicant. It is unclear how the Park reference is being used to meet the limitations of claim 24. This argument was presented by Applicant in the response of July 7, 2003 following the First Office Action, but has not been addressed by the Examiner. The purpose of the closure cap in Applicant's claimed invention is for closing the forward end opening of the syringe to maintain sterility of the syringe barrel and for retaining flowable materials in the syringe barrel.

A claim is anticipated by a reference only if each and every element as set forth in the claim is found in the reference. The Park reference does not anticipate the limitations of claim 24. Accordingly, the Examiner is requested to withdraw this rejection.

- **Specifically regarding the rejection of claim 25:**

The rejection of claim 25 over Park should be withdrawn for the reasons stated above with respect to claim 1, as claim 25 depends directly from claim 1.

- **Specifically regarding the rejection of claim 26:**

The rejection of claim 26 should be withdrawn because the Park reference does not recite a brace means, as claimed by Applicant. The brace means of the instant invention functions to maintain the plunger shaft in a withdrawn position such that the substance in the syringe is not expelled or ejected from the syringe barrel. The brace means restricts the plunger member and piston from movement along and within the syringe barrel until the brace means is removed. It is unclear how the claimed limitations are being met by the Park reference, and what teaching in the reference the Examiner is relying on to meet the limitation. This is a clear structural difference between the Park reference and Applicant's claimed subject matter. This argument was presented by Applicant following the First Office Action, but has not been addressed by the Examiner.

A claim is anticipated by a reference only if each and every element as set forth in the claim is found in the reference. The Park reference does not anticipate the limitations of claim 26. Accordingly, the Examiner is requested to withdraw this rejection.

- **Specifically regarding the rejection of claim 27:**

The rejection of claim 27 over Park should be withdrawn for the reasons stated above with respect to claim 1, as claim 27 depends directly from claim 1.

- **Specifically regarding the rejection of claim 28:**

The rejection of claim 28 over Park should be withdrawn for the reasons stated above with respect to claim 1, as claim 28 depends directly from claim 1.

- **Specifically regarding the rejection of claim 29:**

The rejection of claim 29 over Park should be withdrawn because Park teaches the complete opposite of what Applicant claims regarding automatic recoil of the corrugated sheath after being lengthened or compressed (see column 4, lines 58-62 of Park). Applicant's claim limitation requires that automatic recoil of the corrugated sheath not occur. This is a clear structural and functional difference between the Park reference and Applicant's claimed subject matter. It is unclear how the claimed limitations are being met by the Park reference and what teaching in the reference the Examiner is relying on to met the claimed subject matter.

A claim is anticipated by a reference only if each and every element as set forth in the claim is found in the reference. The Park reference does not anticipate the limitations of claim 29. Accordingly, the Examiner is requested to withdraw this rejection.

- **Specifically regarding the rejection of claim 30:**

The rejection of claim 30 over Park should be withdrawn because Park does not teach that the bellows 86 encloses the length of the plunger existing between the rearward end face surface of the syringe barrel handle member and the forward face surface of the plunger handle member in that bellows 86 of the Park reference is attached to a stopper, which is not a syringe barrel handle member. Additionally, the bellows 86 does not enclose a plunger having an attached piston. Park does not meet the structural limitations of claim 30 or the combination of claims 1 and 30. This is a clear structural difference between the Park reference and Applicant's claimed subject matter.

A claim is anticipated by a reference only if each and every element as set forth in the claim is found in the reference. The Park reference does not anticipate the

limitations of claim 30. Accordingly, the Examiner is requested to withdraw this rejection.

- **Specifically regarding the rejection of claim 31:**

The rejection of claim 31 over Park should be withdrawn because Park does not teach or show that each successive portion of the plunger shaft that exits the rearward end opening of the syringe barrel is enclosed and encircled by the bellows 86 and that each successive portion that exits the bellows 86 passes through said rearward end opening of the syringe barrel. Specifically, bellows 86 is not attached to a syringe barrel handle member, but is attached to a stopper. This is a clear structural and functional difference between the Park reference and Applicant's claimed subject matter. It is unclear how the Park reference is being used to meet the limitations of claim 31.

A claim is anticipated by a reference only if each and every element as set forth in the claim is found in the reference. The Park reference does not anticipate the limitations of claim 31. Accordingly, the Examiner is requested to withdraw this rejection.

- **Specifically regarding the rejection of claim 32:**

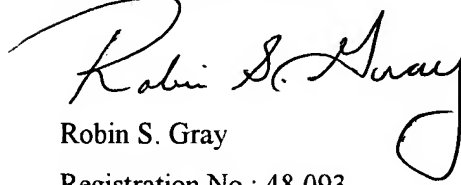
The rejection of claim 32 over Park should be withdrawn for the reasons stated above with respect to claim 1, as claim 32 depends directly from claim 1.

The Applicant is unclear where the Examiner stands on many of the issues raised by Applicant in the response of July 7, 2003 following the First Office Action, because the Examiner has not responded to the all arguments presented in that response. Applicant argued in the July 7, 2003 response that many of the limitations of the dependant claims were not addressed by the Office Action or were clearly inaccurate. Applicant also presented amended claims and new claims in that response, and the Examiner rejected the amended claims and the new claims using the same rejections that were used in the First Office Action without addressing the amendments that were made or the limitations of the new claims. The Examiner's subsequent response of September 10, 2003 to Applicant's arguments did not address Applicant's concerns regarding the Examiner's First Office Action. Further, Applicant does not understand the basis of the rejections for the independent claim and the dependant claims. The rejections in the First and Final Office Actions are duplicates and neither of the rejections addresses all of the claim limitations of the

independent and dependant claims. The Examiner has not explained in the rejections or in response to Applicant's arguments, how the rejections meet the claim limitations. Applicant believes that the art does not anticipate the limitations of the claimed subject matter and that the rejections should be withdrawn.

Applicant respectfully submits that the above arguments place the application for patent in condition for allowance and early notification to that effect is respectfully requested.

Respectfully submitted,

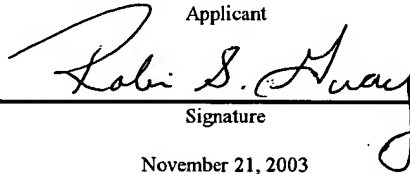

Robin S. Gray

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I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria Virginia 22313-1450, on November 21, 2003.

Robin S. Gray

Applicant



Signature

November 21, 2003

Date of Signature